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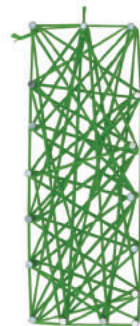
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Part I

Step 1: Creating choice awareness

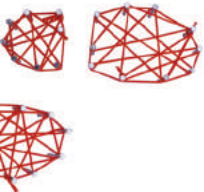


Chapter 2

Deciding about (neo-)adjuvant rectal and breast cancer treatment: Missed opportunities for shared decision making

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Abstract

Background: The first step in shared decision making (SDM) is creating choice awareness. This is particularly relevant in consultations concerning preference-sensitive treatment decisions, e.g., those addressing (neo-)adjuvant therapy. Awareness can be achieved by explicitly stating, as the 'reason for encounter', that a treatment decision needs to be made. It is unknown whether oncologists express such reason for encounter. This study aims to establish 1) if 'making a treatment decision' is stated as a reason for the encounter and if not, what other reason for encounter is provided, and 2) whether mentioning that a treatment decision needs to be made is associated with enhanced patient involvement in decision making.

Material and Methods: Consecutive first consultations with 1) radiation oncologists and rectal cancer patients, or 2) medical oncologists and breast cancer patients, facing a preference-sensitive treatment decision, were audiotaped. The tapes were transcribed and coded using an instrument developed for the study. Oncologists' involvement of patients in decision making was coded using the OPTION-scale.

Results: Oncologists (N=33) gave a reason for encounter in 70/100 consultations, usually (N=52/70, 74%) at the start of the consultation. The reason for encounter stated was 'making a treatment decision' in 3/100 consultations, and 'explaining treatment details' in 44/100 consultations. The option of foregoing adjuvant treatment was not explicitly presented in any consultation. Oncologist' involvement of patients in decision making was below baseline (Md OPTION-score=10). Given the small number of consultations in which the need to make a treatment decision was stated, we could not investigate the impact thereof on patient involvement.

Conclusion: This study suggests that oncologists rarely express that a treatment decision needs to be made in consultations concerning preference-sensitive treatment decisions. Therefore, patients might not realize that foregoing (neo-) adjuvant treatment is a viable choice. Oncologists miss a crucial opportunity to facilitate SDM.

Introduction

Shared decision making with patients (SDM) is particularly relevant when treatment decisions are preference-sensitive, i.e., in the absence of a clinically 'best choice', or when individual patients' valuations of the benefits and harms may strongly vary.¹ Decisions about short-course preoperative radiotherapy (PRT) in rectal cancer and about adjuvant chemotherapy and/or endocrine therapy in early-stage breast cancer are often indeed preference-sensitive.^{2;3} In rectal cancer, PRT decreases the 5-year local recurrence risk from 11% to 6%, but increases the probability of adverse outcomes such as faecal incontinence and sexual dysfunction.^{4;5} There is a high number needed to treat to prevent one local recurrence, without a clearly demonstrated additional overall survival benefit.⁴ For early-stage breast cancer, adjuvant systemic treatment is recommended for patients who have a 10-year recurrence risk of 25% or more, and when treatment would at least yield an absolute recurrence benefit of 10%.³ It has been argued that up to 60% of breast cancer patients only experience harms of adjuvant systemic treatment and loss of quality of life, with little or no survival benefit.⁶ In both the rectal and breast cancer context, the effect of (neo-)adjuvant treatment has been demonstrated,^{4;7} but difficulties arise in selecting those patients who will benefit from treatment. Foregoing these (neo-)adjuvant treatments is a clinically viable option,^{2;3} and given that individual patients may weigh benefits and harms of treatment differently,^{8;9} involving patients in treatment decision making is essential.

In most SDM models, three key steps are distinguished: 1) explaining to the patient that a decision has to be made; 2) discussing all relevant treatment options and their associated benefits and harms; and 3) eliciting patients' ideas, concerns and expectations and supporting patients in the process of deliberation, before reaching a decision.^{1;10;11} Although the first step is pivotal for SDM,¹ it received relatively little attention in the literature so far.¹² Patients facing a decision with marked trade-offs between benefits and harms often report that they were not aware that a treatment decision had to be made.¹³ Yet, most patients, including those with cancer, indicate they want an active role in deciding about treatment.^{14;15} Oncologists can create 'choice awareness' by explicitly stating that making a treatment decision is a 'reason for the

encounter'. To date, there is little evidence on which reason for encounter oncologists express during consultations with cancer patients facing a preference-sensitive treatment decision.

The aims of this study were to establish 1) if 'making a treatment decision' is stated as a reason for the encounter in decision-related consultations on (neo-) adjuvant cancer treatment, and if not, what other reason for encounter is provided, and 2) whether explicitly stating that a treatment decision needs to be made is associated with enhanced patient involvement in decision making.

Materials and methods

Design

A secondary analysis was conducted of data collected in two large ongoing multicentre descriptive studies on (risk) communication during first consultations concerning (neo-) adjuvant therapy.^{16;17} We chose the two contexts of (neo-)adjuvant rectal and breast cancer treatment as they both concern preference-sensitive decisions and allowed us to investigate a broader spectrum of adjuvant treatment consultations between oncologists and cancer patients.

Consecutive first consultations - usually the only consultation prior to the start of the adjuvant treatment - between 1) radiation oncologists and rectal cancer patients, and 2) medical oncologists and breast cancer patients, were audiotaped. The Medical Ethics Committee of the Leiden University Medical Center approved both studies. Eligible patients signed an informed consent form prior to the consultation and completed a questionnaire to assess socio-demographic details, either before (rectal cancer study) or after (breast cancer study) the consultation.

Study population

Participants were recruited in six radiation and four medical oncology outpatient clinics of general teaching and non-teaching hospitals, and university medical centers in the Netherlands. Eligible patients were 1) primary rectal cancer patients eligible for short-course (5x5 Gy) preoperative radiotherapy (clinical stage I-III), or 2) early-stage breast cancer patients eligible for adjuvant chemotherapy and/or endocrine therapy (pathological stage I-III). They were to have a good comprehension of the Dutch language.

All radiation oncologists treating rectal cancer patients and medical oncologists treating breast cancer patients from the participating departments were invited to participate.

Procedure

We aimed to select a sample of 50 consultations each from both study databases using the random sampling function of IBM SPSS Statistics (version 20). In the rectal cancer study, we balanced for gender and included all participating female patients in the present analyses (N=26). An equal number of male rectal cancer patients was then selected at random. Fifty female patients were randomly selected from the breast cancer study. Two patients were excluded from the analyses because of incomplete audiotaping. The 100 patient selected eventually were treated between November 2010 and October 2013.

Measures

Audiotapes of consultations were transcribed verbatim. The coding instrument was self-developed. One coder drafted a first version of the items and categories to code the reason for encounter based on four consultations. These codes were developed inductively, i.e., based on the data. The draft of the coding instrument was then complemented and refined based on 22 subsequent consultations. These were coded again using the final version of the coding scheme. Each

version of the coding scheme was discussed among the authors (MK, EE, FH, AP).

We coded whether 'making a treatment decision' was stated as a reason for encounter (yes/no), and if not, what other reason for encounter was provided (i.e., referral by other clinician, mentioning treatment, explaining treatment details, explaining treatment process; see Table 1, column 1). We further coded when the reason for encounter was stated and how the patient responded to the oncologist's stated reason for encounter (see Table 1, column 1). Utterances of patients' accompanying significant others were coded as the patients', unless the patient contradicted such statements. Finally, we coded whether foregoing adjuvant treatment was explicitly presented as a treatment option (yes/no), and whether a treatment decision was made during the consultation (yes, no, explicitly postponed).

Two raters independently coded the same ten audiotapes (10%) using the final version of the coding scheme. Inter-rater reliability was high (mean Cohen's $K = 0.84$. Range; 0.71-1). One of the raters coded the remaining tapes. Intra-rater reliability, based on ten tapes (10%) coded twice with a time difference of two months, was also high (mean Cohen's $K = 0.94$. Range; 0.65-1).

Next, the OPTION (Observing PaTient InvOlvemeNt) scale was used to quantify the extent to which oncologists involve patients in the decision making process.¹⁸ The OPTION scale measures 12 patient-involving behaviours of clinicians on a 0-4 scale. Inter-rater reliability of two independent raters, based on 10 audiotapes (10%), was substantial (Cohen's $K = 0.66$). The remaining tapes were coded by one of the raters (Intra-rater agreement: Cohen's $K = 0.72$ and 0.93). The overall mean OPTION-scores were converted to a 0-100 scale, with 0 indicating no behaviour of the oncologist to involve the patient in deciding about treatment, to 100 indicating maximum behaviour.¹² A score of 50 is considered to represent baseline skill level.¹²

Statistical analyses

Descriptive statistics were used to establish patients' and oncologists' characteristics, and the statements concerning the stated reasons for the encounter. As OPTION-scores were not normally distributed, medians are presented and compared by reason for encounter mentioned with Mann-Whitney U-tests. Testing was done two-sided at $\alpha=0.05$.

Results

Participants

Twenty radiation oncologists and thirteen medical oncologists audiotaped a median of three consultations (range, 1-7). Patients were on average 61.8 years old (range, 37-87).

Reasons for encounter provided

A reason for encounter was provided in 70/100 consultations (70%). The oncologists explicitly stated, as a reason for encounter, that a treatment decision needed to be made in 3/100 consultations (3%, Table 1). In these cases the oncologist invited patients to participate in deciding about adjuvant treatment by using the phrases "whether you want this adjuvant treatment", "you can decide whether or not you want to do it" or "if you agree with the proposed treatment". Across contexts, most often (N=44/100, 44%), the oncologists indicated the reason for encounter to be 'explaining the treatment details'. In 17/100 consultations (17%), oncologists stated that the patient was there 'for the treatment' (e.g., radiotherapy or chemotherapy, and/or endocrine therapy), without specifying what they would discuss. In 30/100 consultations, the oncologists provided no reason for encounter.

Table 1. Reasons for encounter (frequencies) stated

	Total N (%)	Rectal cancer N (%)	Breast cancer N (%)
All consultations	N=100	N=51	N=49
What was the oncologist’s stated reason for encounter?			
Making a treatment decision Example: “ <i>Well, the idea is that we just... give you the treatment as we normally do, but in light of this consultation, you can decide whether or not you... want to do it.</i> ”	3/100	2/51 (4)	1/49 (2)
Explaining treatment details Example: “ <i>Well, the purpose of this consultation is for me to talk to you about radiotherapy, why, what you can expect, and what the side effects are.</i> ” or “ <i>You are here to talk about adjuvant treatment. You might benefit from chemotherapy and endocrine therapy</i> ”	44/100	20/51 (39)	24/49 (49)
Mentioning treatment Example: “ <i>So mrs. P, you have come today for the first consultation about the radiotherapy... of the rectum.</i> ”	17/100	14/51 (27)	3/49 (6)
Referral by other clinician Example: “ <i>Okay, you have come... you were referred... for radiotherapy</i> ”	5/100	3/51 (6)	2/49 (4)
Explaining treatment process Example: “ <i>What we are going to do. We... we are going to explain the whole course of treatment with radiotherapy and the surgery. And... then we are going to sort it all out for you.</i> ”	1/100	1/51 (2)	0
No reason for encounter stated	30/100	11/51 (22)	19/49 (39)
All reasons for encounter	N=70	N=40	N=30
When was the reason for encounter stated?			
At the start of the consultation	52/70 (74)	33/40 (83)	19/30 (63)
At the start, but after a summary of the disease/treatment process so far	10/70 (14)	3/40 (7)	7/30 (23)
After history taking	6/70 (9)	2/40 (5)	4/30 (13)
After (part of) information provision on treatment	2/70 (3)	2/40 (5)	0
How did the patient respond?			
No reaction or minimal response Example: “ <i>Yeah</i> ”, “ <i>Okay</i> ” or “ <i>Hmm</i> ”	55/70 (79)	32/40 (80)	23/30 (77)
Agreement Example: “ <i>Yes, that’s right</i> ”	12/70 (17)	6/40 (15)	6/30 (20)
Surprise Example: “ <i>Oh, is that why I’m here?</i> ”	3/70 (4)	2/40 (5)	1/30 (3)

If the oncologist stated a reason for encounter, this was usually (N=52/70, 74%) done at the start of the consultation (Table 1). Patients mostly (N=55/70, 79%) reacted minimally or not at all to the oncologist's reason for encounter (Table 1). Patients sometimes (N=12/70, 17%) responded by stating that their understanding of the reason for encounter was similar to that of the oncologist, and in a few instances (N=3/70, 4%) by stating that the oncologist's reason for encounter surprised them.

Treatment decision making

In none of the consultations, including those in which the oncologist stated that a treatment decision needed to be made, the option of foregoing (neo-)adjuvant treatment was explicitly presented as a possible strategy.

A treatment decision was made in 56/100 consultations. The decision was explicitly postponed in 9/100 consultations, of which two concerned rectal, and seven breast cancer patients. In all other cases (N=35/100), the treatment decision seemed to have been made before the start of the consultation ("You are here because of your bowel cancer, basically, we will give you a short series of radiotherapy followed by surgery.").

Patient involvement in treatment decision making

Patient involvement in decision making amounted to a median score of 10 (range, 2-60) on a 0-100 scale. Given that only in three consultations decision making was mentioned as a reason for encounter, we could not investigate the association with patient involvement, but in these three consultations, the oncologists showed more behaviour to involve patients than the average (13,17 and 38).

Discussion

Involving patients in treatment decision making is related with improved satisfaction of patients with care and with the decision, and less anxiety and decisional conflict in patients.¹⁹ SDM is especially important when treatment decisions are preference-sensitive.¹ Yet, even then patients often are not aware that a treatment decision needs to be made.¹³ Oncologists can create choice awareness in patients and facilitate SDM by explicitly stating, as a reason for encounter, that a treatment decision needs to be made. To the best of our knowledge, the current study is the first to assess whether choice awareness is created in preference-sensitive decision consultations.

In this study, we examined the reasons for encounter given during first consultations of oncologists and cancer patients facing a preference-sensitive decision concerning (neo-)adjuvant cancer treatment. In only 3% of the consultations the need to make a treatment decision was found to be made explicit. Rather, the oncologists indicated that the reason for encounter was for them to explain the treatment details. Interestingly, in none of the 100 consultations, including those in which the need to make a treatment decision was expressed, the option of foregoing (neo-)adjuvant treatment was explicitly addressed. This is not in line with informed consent norms. Moreover, choosing between two possible treatment strategies might feel less burdensome to patients than declining the one treatment the oncologist has on offer.²⁰ Only if patients are offered a balanced view of possible treatment strategies, they will be prevented from consenting to treatments that go against their informed values and preferences.²¹⁻²³

In this study, we also aimed to assess whether explicitly mentioning that a treatment decision needs to be made is associated with enhanced patient involvement in decision making. Unfortunately, we were unable to do so because oncologists expressed this need to make a treatment decision in almost none of the consultations.

Patient involvement in the decision making process was quite low. This is reflected by the OPTION-scores as compared to other studies in oncology using this scale and to the norm for baseline skills.¹² A possible explanation for the low level of patient involvement is that in roughly one-third of the consultations a treatment decision seemed to have been made before the start of the consultation. This most probably had been done during the multidisciplinary team (MDT) meeting. Oncologists might then consider the treatment recommendation from the MDT as the one best treatment, thus leaving less room for patients' values and preferences to be incorporated in the final decision. In previous research, we also showed that oncologists' behaviour to involve patients in treatment decision making was limited, but that at the same time, oncologists do believe they apply the principles of SDM in daily practice.²⁴ Our findings reflect the limited skills of the oncologists in SDM and points to the need for thorough training to support the implementation of SDM in clinical practice.

A strength of our study is that we were able to observe actual communication in a broad spectrum of consultations between oncologists and cancer patients and that we did not depend on oncologists' or patients' recall or interpretation on whether 'making a treatment decision' was addressed. A possible limitation of our study is that although the Dutch national rectal and breast cancer treatment guidelines provide room to opt for different treatment strategies,^{2,3} we do not have information on the extent to which oncologists perceived a treatment choice. Future research should therefore focus on assessing oncologists' perceptions of the viability of declining adjuvant treatment, and especially on oncologists' reasoning behind these perceptions. Given that patients' valuations of treatment and of benefits and harms of treatment vary,^{8,9} and given that the treatment guidelines already consider these treatment decisions to be preference-sensitive,^{2,3} choice awareness might have to be created in oncologists as well.

In conclusion, creating awareness of treatment choice is considered to be pivotal for SDM, but it has received little attention in the literature so far. Our results show that during preference-sensitive decision consultations on adjuvant

cancer treatment, oncologists rarely express that a treatment decision needs to be made. Thus, they miss a crucial opportunity to create choice awareness in patients and engage patients in an SDM process. Instead, oncologists seem to use the consultation to explain the one treatment strategy they recommend. We expect that creating awareness in patients of treatment choice, thus taking the first step of SDM, will provide more opportunities for oncologists and patients to collaborate in selecting the best possible course of action and thus improve patient outcomes. Indeed, adequately creating choice awareness among patients might be a simple, cheap, yet effective step in empowering patients to participate in treatment decision making and helping them to receive the treatment that is in accordance with their values and preferences.

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